

REMARKS

Claims 1-12 and 31-42 are currently pending, and have been rejected in the outstanding office action. Reconsideration is requested.

Rejections Under 35 U.S.C. §102

Claims 1-2, 4-12, 31-32 and 34-42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Yoon (U.S. Patent No. 5,542,949). Claim 1 is set forth below:

1. An apparatus for forming a lumen from within an hollow body organ, comprising:
 - a tissue positioning device having a first opening in a first region for releasably adhering a first area of tissue and a second opening in a second region for releasably adhering a second area of tissue thereto, the first and second openings being separated by a septum;
 - at least one fastener housed within the device; and
 - wherein the septum being removable from between the first and second openings to allow the at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue via the fastener.

Yoon, upon which the first rejection of Claim 1 is based, purports to disclose a clip applying instrument with distal jaws spring biased apart, and surgical clips disposed in one or two clip magazines removably received in the instrument body. A handle is used to grasp and manipulate tissue when no clip is in the jaws, to advance clips into the jaws, and to cut tissue after clipping. [Abstract]. A major stated purpose of the Yoon device is to avoid repeated withdrawal of the instrument to load a new clip by utilizing an automatic clip feed mechanism. The device includes suction and irrigation tubes and a cutting instrument for cutting tissue.

Claim 1 recites as part of the claimed apparatus a tissue positioning device. The Office Action cites to element 42 of Yoon, which is a hollow cylinder. [Col. 3, lines 33-34] The hollow cylinder 42 of Yoon has a first opening as recited in Claim 1, but it is not port 86 as asserted by the Office Action, as this is not part of cylinder 42. Rather, the opening of cylinder 42 as shown in Figure 5 of Yoon merely allows the clamping device

to slide within. So the Office Action's first contention that cylinder 42 satisfies the claimed tissue positioning device of Claim 1 is incorrect.

Second, tube 86 does not come into contact with any tissue and Yoon fails to teach that it "releasably adher[es] a first area of tissue." The Office Action cites to column 3, lines 51 – 55 and column 7, lines 9 – 24. The citation to column 3 speaks to the port permitting "suction and/or irrigation." The citation at column 7 explains the first citation, stating that "if during a procedure it is desired to evacuate or aspirate **fluid** from the operative side, valve 62 can be coupled with a vacuum source to create suction through the inner cylinder 89 via passages or tubes 86 and 88 which open at the distal ends of the jaws 46 and 48, respectively." Thus, the ports are used for supplying or removing fluid, not positioning tissue, and there is no teaching in Yoon of the claimed feature.

It is black letter patent law that anticipation under 35 U.S.C. §102 requires "identity of invention:" the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1267, 20 USPQ2d 1746, 1748 (Fed.Cir. 1991); see also In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). Here, the Office Action has failed to show where in Yoon the claimed feature because nowhere in the Yoon disclosure is there any teaching of the claimed tissue positioning device.

Claim 1 also calls for the first and second openings to be separated by a septum. The term "septum" has a well understood meaning in the art, and serves a well understood purpose. Anticipation rejections are not subject to manipulation of what the disclosed device could do if certain modifications were made, but rather is limited to what the purported reference actually teaches. Here, the Office Action contends that cutting member 223 and case 228 satisfy the limitation of the septum. But cutting member 223 cannot just be characterized as a septum without further explanation. Yoon

does not assert that it serves any "septum-like" purpose, and the Office Action does not explain why the cutting member satisfies the septum limitation.

Also, there is no evidence of record that the cutter member 223 is "removable from between the first and second openings." That is, there is no evidence that the cutter member 223 ever achieves a position between the openings 86,88, so there is no evidence that the cutting member is "removable **from between** the first and second openings." Again, the Office Action is not permitted to speculate on what the Yoon disclosure teaches, but must rely on the actual teachings found within the four corners of the Yoon reference in order to satisfy the requirements for a *prima facie* rejection for anticipation. Yoon is silent on where the cutting device is deployed with respect to the ports 86,88. Accordingly, the rejection based on Yoon must be withdrawn, or evidence of record presented that substantiates the positions taken by the Office Action but silent in Yoon.

Further, Claim 1 calls for at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue. The first area of tissue is what is adhered to the first opening, and the second area of tissue is adhered to the second opening. Although there is no evidence that Yoon's ports serve any purpose besides aspiration and evacuation of fluid, even if the ports did adhere tissue as the Office Action contends, there is no disclosure in Yoon that these two areas of tissue are then secured together by the clip of Yoon. Particularly since Yoon places his tubes 86,88 on the outside periphery of the device to permit irrigation and suction, and it would be impossible to then clip tissue adhered to the outside surfaces where tubes 86,88 are located with the device of Yoon. Thus, the rejection of Claim 1 based on Yoon must be withdrawn for this reason as well.

In addition, the Yoon device only discloses that tissue is cut with the cutter device **after** the clip is in place. Yoon states, "when it is desired to cut tissue after a clip has been applied," [Col. 6, lines 62-64] Thus, there is no teaching in Yoon of "the septum being removable from between the first and second openings **to allow** the at least one fastener to be deployed" Since the clip of Yoon is already deployed, the cutter

cannot serve the claimed septum and there can be no anticipation for this independent reason.

It is clear from the foregoing that Yoon does not present the required "identity of invention" that is required for a Section 102 rejection. Applicant has identified no less than six limitations of Claim 1 that is not found in Yoon, or that the Office Action has not established with the required evidence of record. As such, the rejection of Claim 1 based on Yoon is properly withdrawn.

As for Claim 6, the Office Action contends that a vacuum is created in the first and second regions (from Claim 5) and that the first and second regions are in fluid communication with a common channel. The Office Action cites to element 89, but this element is the inner hollow cylinder but is not in "fluid communication" with the two vacuum regions. There could be no vacuum applied in Yoon if there were fluid communication with the cylinder 89, and the whole purpose of the vacuum would be frustrated. Thus, Claim 6 is not anticipated for yet another independent reason.

Claim 31 is similar to Claim 1, and the remarks set forth above with respect to Claim 1 are repeated and incorporated by reference with respect to Claim 31. Applicant therefore requests that the rejection of Claim 31 also be withdrawn.

Claim 1 also stands secondarily rejected as anticipated by Adams et al., U.S. Patent No 6,585,144. Claim 1 calls for "an apparatus for forming a lumen from within a hollow body organ." The Office Action counters that Adams teaches "a stapler device." The first opening of Claim 1 is asserted to be the staple forming groove 19, and the second opening of Claim 1 is asserted to be the staple slits 34. Clearly these two structures cannot meet the claim limitations in order to satisfy the requirements for anticipation. First, how can the port where staples are emitted possibly have tissue adhered thereto? Applicant respectfully submits that the presence of the staple precludes any tissue from being adhered to the staple slit, and that there is no teaching in Adams that the staple forming groove 19 has tissue adhered thereto either.

Also, there is no teaching in Adams that a first area of tissue is secured to a second area of tissue, and clearly not first area of tissue adhered to the staple groove and a second area adhered to the staple slit. There is nothing resembling this teaching in Adams, and the rejection while imaginative is not supported by the record.

The Office Action contends that the "septum" is satisfied by Adams' staple retainer 623. It appears that the Office Action has misunderstood the purpose of the retainer, which stays in place during the stapling procedure than thus does not meet the limitations of Claim 1. Namely the retainer 623 of Adams is not "removable between the first and second openings to allow the at least one fastener to be deployed." Because the whole purpose of the retainer is to remain in place between the staple slit and staple groove while the staple is ejected, there is no teaching of the claimed invention and the rejection based on Adams is properly withdrawn.

Claim 5 calls for the first area of tissue and the second area of tissue to be adhered to the tissue positioning device via a vacuum. The only way this can be accomplished is if the staple groove and the staple slit have vacuum applied therein, since these are the only locations where the first and second areas of tissue are found according to the Office Action. But since there is no vacuum in the staple slit or groove 19,34, there is clearly not anticipation of Claim 5 based on Adams. As for Claim 6, there is no fluid channel in fluid communication with the staple slit and staple groove as required in Claim 6, so there can be no anticipation of Claim 6 as well. Clearly the retainer 623 is not "longitudinally positioned in the tissue positioning device," and the rejection of Claim 10 is also improper. Further, there is no disclosure in Adams that the retainer 623 abrades tissue or that it is even capable of abrading tissue, much less using "heat" as asserted by the Office Action. Without support for the rejection, the rejection cannot stand and is properly withdrawn.

Claim 31 is similar to Claim 1, and the arguments set forth above with respect to Claim 1 based on Adams are repeated and incorporated herein by reference with respect to Claim 31. Based on the foregoing, it is clear that the rejections based on Adams and

Yoon are improper and fail to establish a *prima facie* case of anticipation. Since all of the outstanding rejections are based on one of these two rejections, Applicant respectfully asserts that the claims as presented are now in condition for allowance.

Applicants respectfully submit that claims 1-12 and 31-42 are patentable over Yoon and Adams et al. and that all pending claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited. The Commissioner is authorized to charge deposit account no. 06-2425 for any unforeseen fees arising from the filing of this paper.

Respectfully submitted,

FULWIDER PATTON LLP

By: /michael j. moffatt/
Michael J. Moffatt
Registration No. 39,304

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201